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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/824,847	04/04/2001	Virender K. Sharma	00B-2027	9958

22447 7590 08/27/2002

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[REDACTED] EXAMINER

WARE, TODD

ART UNIT	PAPER NUMBER
1615	3

DATE MAILED: 08/27/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/824,847	SHARMA ET AL.	
	Examiner	Art Unit	
	Todd D Ware	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 25 February 2002.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-16 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Receipt of change of address filed 2-25-02 is acknowledged.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
3. Claims 1-6 and 16 all recite a method for the formulation and delivery of an acid-labile pharmaceutical, however only steps for the formulation of the composition are recited no steps for delivery of the agent are provided.
4. Recitation of "from among at least the group of" does not recite Markush language as provided in MPEP 2173.05(h) and this language does not "close" the Markush group. It is improper to use terminology such as "comprising" instead of "consisting of." *Ex parte Dotter*, 12 USPQ 382. Amendment with "selected from the group consisting of" for each instance where "from among at least the group of" appears would overcome this rejection.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Art Unit: 1615

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-10 and 12-16 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Bengtsson et al (WO 95/01783; hereafter '783).

7. '783 discloses a method of making and a composition comprising salt forms of the acid-labile pharmaceutical compound omeprazole where omeprazole is combined with a basic salt of magnesium (C 3, L 3-35; C 4, L 1-67). No patentable weight is afforded the process limitations of the composition claims.

8. Claims 1-10 and 12-16 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Oishi et al (JP 05-194225; hereafter '225).

9. '225 discloses acid-labile pharmaceutical compounds such as omeprazole, lansoprazole, and rabeprazole mixed with buffers, such as calcium carbonate, aluminum hydroxide and magnesium hydroxide, that maintain weakly alkaline pH in the range of 8-9 (abstract; end of paragraph 0002 of machine translation through middle of paragraph 0003 of machine translation; examples; claims). '225 also discloses enterically coating the dosages (paragraph 0005 of machine translation).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

Art Unit: 1615

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bengtsson et al (WO 95/01783; hereafter '783).

13. '783 teaches a method of making and a composition comprising omeprazole salt forms where omeprazole is combined with a basic salt of magnesium (C 3, L 3-35; C 4, L 1-67). Amount of salt would have been obvious to one skilled in the art at the time of the invention upon adjustment of the amount of salt with the motivation of a desire to use a lesser or greater volume of salt or to achieve a desired thickness of subcoating layer. Furthermore, the amount of salt would have been obvious to one skilled in the art at the time of the invention with the motivation of increasing or decreasing buffer commensurate with the amount of active agent in the dosage form. No patentable weight is afforded the process limitations of the composition claims.

Art Unit: 1615

14. Claims 1-16 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Oishi et al (JP 05-194225; hereafter '225).

15. '225 teaches acid-labile pharmaceutical compounds such as omeprazole, lansoprazole, and rabeprazole mixed with buffers, such as calcium carbonate, aluminum hydroxide and magnesium hydroxide, that maintain weakly alkaline pH in the range of 8-9 (abstract; end of paragraph 0002 of machine translation through middle of paragraph 0003 of machine translation; examples; claims). '225 also discloses enterically coating the dosages (paragraph 0005 of machine translation). Amount of salt would have been obvious to one skilled in the art at the time of the invention with the motivation of increasing or decreasing buffer commensurate with the amount of active agent in the dosage form. No patentable weight is afforded the process limitations of the composition claims.

Conclusion

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Todd D Ware whose telephone number is (703) 305-1700. The examiner can normally be reached on M-F, 8:00 AM - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703)308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Application/Control Number: 09/824,847
Art Unit: 1615

Page 6

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

tw
August 25, 2002

[Signature]
THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600